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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/591,632	06/09/2000	Susan Lindquist	27373/34978A	2820

7590 01/16/2008

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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
01/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/591,632	LINDQUIST ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *67,81,101,103-110,117,118,121-135,137-140 and 143-162* is/are pending in the application.

4a) Of the above claim(s) *67,81,101,103-110,117,118,143,146-149,156 and 162* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,121-135,137-140,144,145,150-155 and 157* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 31, 2007 has been entered.

DETAILED ACTION

Response to Amendment

2. Claims 124, 127, 132-133, 144 and 150 have been amended as requested in the amendment filed on October 31, 2007. Following the amendment, claims 67, 81, 101, 103-110, 117, 118, 121-135, 137-140, 143-162 are pending in the instant application.

3. Claims 67, 81, 101, 103-110, 117, 118, 143, 146-149, 156 and 162 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Papers filed on May 13, 2002 and May 09, 2005.

4. Claims 121-135, 137-140, 144, 145, 150-155 and 157-161 are under examination in the instant office action.

5. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

6. Applicant's arguments filed on October 31, 2007 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 121-135, 137-140, 144, 145 and 157-161 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 124 recites a purified polypeptide comprising amino acid sequence that is at least 90% identical to the fragment 2-113 of SEQ ID NO: 2, wherein the amino acid sequence comprises cysteine, lysine, glutamate, aspartate or arginine at the position 2 of SEQ ID NO: 2. It is not obvious how the amino acid sequence of the claimed polypeptide can "comprise an amino acid [...] at the position [...] 2 of SEQ ID NO: 2", and therefore, the structure of the claimed polypeptide is vague and ambiguous. Recitation of a substituted amino acid residue at the specific position, if this is what Applicant intends to claim, would obviate this ground of rejection.

10. Similarly, claim 127 recites a purified polypeptide comprising amino acid sequence that is at least 90% identical to the fragment 2-253 of SEQ ID NO: 2, wherein the amino acid sequence comprises cysteine or arginine at the position 184 of SEQ ID NO: 2. If the claimed polypeptide differs from SEQ ID NO: 2 at the position 184 by way of substitution for

cysteine or arginine, then that is what the claim should specifically recite in order to delineate the structure of the claimed product.

11. Claims 125 and 128 are vague and indefinite for reciting limitation "exactly one of said amino acids". Claim 125 depends from claim 124 and claim 128 depends from claim 127, which appear to be limited to one substitution of one residue within SEQ ID NO: 2, therefore, claims 125 and 128, as written, do not make sense. Clarification is required.

12. Claims 144 and 145 are vague and ambiguous because the structure of the claimed polypeptide cannot be envisioned as currently claimed. Specifically the claimed polypeptide comprises an amino acid sequence of SEQ ID NO: 2 with a substitution of one amino acid residue (at position 184 in claim 144 or position 2 in claim 145) "or comprising a fragment thereof that includes said substituted amino acid", or a fragment of 50 amino acids. The structural relationship between "a fragment thereof", "said substituted amino acid" or if the "50 amino acids" are added randomly or as a contiguous stretch is not obvious and cannot be determined from the claims or the instant specification.

13. Claim 157 recites the limitation "fiber" in claim 155. There is insufficient antecedent basis for this limitation in the claim.

14. Claims 121-123, 126, 129-135, 137-140 and 158-161 are indefinite for being dependent from indefinite claims.

15. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. Claims 121-123, 139-140, 144-145, 150-155 and 157-161 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for those reasons of record as set forth in section 07 of Paper mailed on May 24, 2007. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Briefly, claims 121-123, 139-140, 144-145, 150-155 and 157-161 encompass fragments of a polypeptide of SEQ ID NO: 2, fragments of the fragments of the polypeptide of SEQ ID NO: 2, fragments of the polypeptides with a limited structural similarity to the polypeptide of SEQ ID NO: 2, and molecular embodiments, which are sequence variants of the above recited fragments (defined as having insertions, additions, deletions and substitutions within the variant sequence, see claim 150, for example), wherein the claimed fragments have the ability to self-coalesce into ordered aggregates. The claims do not require that the recites fragments possess any particular conserved structure or other disclosed distinguishing feature, which supports the ability of the fragments to form ordered aggregates. The instant specification fails to describe the genus of the claimed fragments, and, as such, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore the claims, which encompass the various fragments of the polypeptide of SEQ ID NO: 2 do not meet the written description provision of 35 U.S.C. §112, first paragraph.

Applicant traverses the instant rejection by stating that "[t]he specification discloses that amino acid composition rather than any particular conserved sequence underlies the property of self-coalescence. Thus one structural feature of self-coalescing sequences is that they are rich in

the amino acids glutamine, aspargine, glycine, and possibly the polar residues serine and tyrosine"" (pp. 14-15 of the Response). Applicant argues that "(i) the claims are not of "limitless breadth" since they recite fragments of specific sequences and fragments of variants of these sequences; and (ii) the specification provides considerable guidance as to the characterization of fragments that would be expected to self-coalesce" (p. 16). Applicant further refers to *Falkner v. Inglis* to state that there is no rule to require recitation of known structure and the CAFC decision of *Enzo.* Applicant's arguments have been given careful consideration but not found to be persuasive for the following reasons.

Claims 121-123, 139-140, 144-145, 150-155 and 157-161 are drawn to a genus of proteins with a limited (fragments of certain length or percent identity) or no structural similarity (fragments of fragments with additions, deletion or substitutions and variants thereof) to the polypeptide of SEQ ID NO: 2, wherein the claimed molecules have the ability to coalesce into aggregates, which defines their practical utility. The Examiner maintains that the instant specification fails to provide adequate written description to support the genus of polypeptides and fragments thereof to satisfy the requirement of the first paragraph of section 112.

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. EliLilly and Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997 (bracketed material in original). The claims in *Lilly* were directed generically to vertebrate or mammalian insulin cDNAs. See id. at 1567, 43 USPQ2d at 1405. The court held that a structural description of a rat cDNA was not an adequate description of these broader classes of cDNAs.

The *Lilly* court explained that

> a generic statement such as... 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus.

Id. at 1568, 43 USPQ2d at 1406. The *Lilly* court set out exemplary ways in which a genus of cDNAs could be described:

> A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

Id. at 1569.

This standard applies to polypeptides as well as DNAs. *See University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 925, 69 USPQ2d 1886, "893 (Fed. Cir. 2004).

The instant claims are drawn to polypeptides, fragments and variants of the fragments with limited or no structural similarity to the polypeptide of SEQ ID NO: 2, wherein the fragments self coalesce into ordered aggregates. The specification does not disclose how large is the encompassed genus, or any distinguishing structural characteristics of the claimed polypeptides so that a skilled artisan could easily visualize what is claimed, and also does not disclose a single variant that meets the limitation of section (e) of claim 150, for example. In addition, there is no disclosure of sufficiently detailed, relevant identifying characteristics, such as other physical and/or chemical properties, or functional characteristics, that when coupled

with a known or disclosed correlation between function and structure (i.e., the sequence), or some combination of such characteristics, would constitute an adequate written description of the claimed invention. All that is disclosed is the amino acid sequence and that substitutions of the certain residues within this amino acid sequence lead to spontaneous aggregation of the polypeptide. Just as in the *University of Rochester* case, the present application discloses a broad genus of chemical compounds (polypeptides having sequence identity to SEQ ID NO: 2 or fragments and variants thereof) but the claims are limited to only those compounds having a desired characteristic (proteins that self coalesce into ordered aggregates). Thus, the present specification does not disclose which proteins that meet the structural characteristics of the claims are also able to self aggregate. Granted, those skilled in the art could screen libraries of proteins that meet the structural description of the instant claims to identify for themselves specific proteins that self coalesce into ordered aggreagets. That, however, does not make up for the deficiency of the specification's description. The *University of Rochester* court specifically noted that the patent at issue there disclosed screening assays to identify compounds having the desired characteristic, but nonetheless held that the description was inadequate.

As the skilled artisan cannot visualize the full breadth of the genus of the claimed compounds, the claims fail to meet the written description requirement of 35 USC 112, first paragraph, and the rejection is maintained.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. Claims 150 and 151 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kushnirov et al., 1988 (Gene, 66, pp. 45-54).

Claims 150 and 151 are drawn to polypeptides comprising a fragment of SEQ ID NO: 2 labeled with a fluorescent dye. Due to the use of "comprising" language, the claims encompass the full length of Sup35 polypeptide, first described by Kushnirov et al. in 1988, with a label attached to it. While document of Kushnirov et al. discloses only the structure of polypeptide of

SEQ ID NO: 2 and does not explicitly disclose labeling of the polypeptide, the art of conjugating polypeptides with various labels for purposes of protein identification, for example, is old and well-known.

At the time of invention, it would have been *prima facie* obvious for one of ordinary skill in the art to label the protein as disclosed by Kushnirov et al.. One of ordinary skill in the art would have been motivated to do this for purpose of protein identification, for example.

Double Patenting

21. Applicant is advised that should claim 127 be found allowable, claims 130 and 131 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Specifically, claims 130 and 131 further describe the polypeptide claimed in claim 127 without adding any limitations to define any difference in structure, which makes the subject of the claims indistinguishable.

Similarly claims 121, 122 appear to be a substantial duplicate of claim 144 because the dependent claims do not add any limitation that would allow to further limit or distinguish the structure of the claimed products of the base claim.

Conclusion

22. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

January 14, 2008